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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/764,978  | 01/23/2004  | Plamen Denchev       | 205502-9037         | 9303             |
| MICHAEL BEST & FRIEDRICH LLP Two Prudential Plaza         |             |                      | EXAMINER            |                  |
|   |             |                      | HWU, JUNE           |                  |
| 180 North Stetson Avenue, Suite 2000<br>CHICAGO, IL 60601 |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1661                |                  |
|   |             |                      |                     |                  |
|   |             |                      | MAIL DATE           | DELIVERY MODE    |
|   |             |                      | 01/16/2008          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | <u></u>   | Application No.  | Applicant(s)   |  |  |  |  |
|--|---|--|--|--|--|--|--|
| Office Action Summary  |   | 10/764,978.  | DENCHEV ET AL.   |  |  |  |  |
|  |   | Examiner   | Art Unit   |  |  |  |  |
|  |   | June Hwu   | 1661   |  |  |  |  |
|  | The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply   |  |  |  |  |  |  |
| WHIC<br>- Exte<br>after<br>- If NC<br>- Failu<br>Any   | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION  36(a). In no event, however, may a reply be tin  will apply and will expire SIX (6) MONTHS from  cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |  |
| Status   |   |  |  |  |  |  |  |
| 1)⊠  | Responsive to communication(s) filed on 13 November 2007.   |  |  |  |  |  |  |
| 2a)  | This action is <b>FINAL</b> . 2b)⊠ This action is non-final.  |  |  |  |  |  |  |
| 3)   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is   |  |  |  |  |  |  |
|  | closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.   |  |  |  |  |  |  |
| Disposit   | ion of Claims   |  |  |  |  |  |  |
| 4)⊠  | Claim(s) <u>1,5-9,12,14,16-23,27,28,33,34,36-43 and 50-60</u> is/are pending in the application.  |  |  |  |  |  |  |
| _  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |  |
| -  | Claim(s) is/are allowed.  |  |  |  |  |  |  |
| ·  | Claim(s) <u>1,5-9,12,14,16-23,27,28,33,34,36-43 and 50-60</u> is/are rejected.  |  |  |  |  |  |  |
| 7)⊠<br>8)□   |   |  |  |  |  |  |  |
| Opin Claim(a) are subject to restriction and/or election requirement.  |   |  |  |  |  |  |  |
|  | ion Papers  |  |  |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |  |  |  |  |  |  |
|  | Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. |   |  |  |  |  |  |  |
|  |   | ammer. Note the attached office  | Action of form 10 102.   |  |  |  |  |
| Priority (   | under 35 U.S.C. § 119   |  |  |  |  |  |  |
| -  | Acknowledgment is made of a claim for foreign  All b) Some * c) None of:  |  | )-(d) or (f).  |  |  |  |  |
| 1. Certified copies of the priority documents have been received.  |   |  |  |  |  |  |  |
| <ul> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>                  |   |  |  |  |  |  |  |
| application from the International Bureau (PCT Rule 17.2(a)).  |   |  |  |  |  |  |  |
| * See the attached detailed Office action for a list of the certified copies not received.   |   |  |  |  |  |  |  |
|  |   | <b>4</b> 1   |  |  |  |  |  |
| Attachmen  |   | <b>,,</b> □,,,,,,  |  |  |  |  |  |
|  | ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)   | 4)   |  |  |  |  |  |
| 3) Infor   | mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date   | 5) Notice of Informal F  |  |  |  |  |  |

### **DETAILED ACTION**

The amendment to the claims filed on November 13, 2007 is acknowledged and entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office action.

## Status of the Claims

Claims 2-4, 10-12, 15, 24-26, 29-32,35, and 44-49 are cancelled and claims 1, 5-9, 13, 14, 16-23, 27, 28, 33-34, 36-43, and 50-60 will be examined on the merits.

The objection of claim 10 under 37 CFR 1.75(c) is withdrawn due to Applicants amendment of the claim.

## Objections to the Claims

Claims 5, 20, 27, 41, 54 and 60 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 1 is drawn to a method of for reproducing coniferous somatic embryos, wherein the nutrient medium comprises lactose. Claim 5 is drawn to the method of claim 1, wherein lactose is less than 6.0% of the nutrient medium. The amount of lactose would be between 0 to 6%. Thus, claim 5 is broader than claim 1.

Claim 1 is drawn to a method of for reproducing coniferous somatic embryos, wherein the nutrient medium comprises lactose. Claim 20 is drawn to the method of claim 1, wherein

lactose is less than 2.0% of the nutrient medium. The amount of lactose would be between 0 to 2%. Thus, claim 20 is broader than claim 1.

Claim 23 is drawn to a method of for reproducing *Pinus taeda* or hybrid thereof somatic embryos, wherein the nutrient medium comprises lactose. Claim 27 is drawn to the method of claim 23, wherein lactose is less than 6.0% of the nutrient medium. The amount of lactose would be between 0 to 6%. Thus, claim 27 is broader than claim 23.

Claim 23 is drawn to a method of for reproducing *Pinus taeda* or hybrid thereof somatic embryos, wherein the nutrient medium comprises lactose. Claim 41 is drawn to the method of claim 23, wherein lactose is less than 2.0% of the nutrient medium. The amount of lactose would be between 0 to 2%. Thus, claim 41 is broader than claim 23.

Claim 50 is drawn to a method of for reproducing coniferous somatic embryos, wherein the nutrient medium comprises lactose. Claim 54 is drawn to the method of claim 50, wherein lactose is less than 6.0% of the nutrient medium. The amount of lactose would be between 0 to 6%. Thus, claim 54 is broader than claim 50.

Claim 55 is drawn to a method of for reproducing somatic embryos, wherein the nutrient medium comprises galactose-containing sugar. Claim 60 is drawn to the method of claim 55, wherein galactose-containing sugar is less than 6.0% of the nutrient medium. The amount of galactose-containing sugar would be between 0 to 6%. Thus, claim 60 is broader than claim 55.

# Claim Rejections - 35 USC § 103

Claims 1, 5-9, 12, 13, 16-23, 27, 28, 33, 34, and 36-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Attree (U.S. Patent No. 6,627,441) in view of Handley et al (U.S. Patent No. 5,491,090). The rejection is repeated for reasons of record as set forth in the

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Office Action mailed August 10, 2007 as applied to claims 1, 5-10, 12-14, 18-23, 27, 28, 33, 34, and 36-43.

The claims are drawn to a method of reproducing coniferous somatic embryos are selected from the family *Pinaceae* including *Pinus taeda* or hybrid thereof and *Picea* comprising growing an embryogenic culture derived from an explant on a nutrient medium selected from the group consisting of induction, maintenance, or prematuration media, wherein the nutrient medium comprises of lactose which is more than 1.0% and less than 6.0% of the medium and an additional sugar selected from the group consisting of sucrose, glucose or fructose, wherein the additional sugars are readily metabolized. The nutrient medium further comprises of less auxin, less cytokinin and abscisic acid (ABA) in the prematuration medium, wherein the medium could be gelled or liquid. The induction medium is used to induce embryogenic tissue, the prematuration medium is used to grow and maintain embryogenic culture and the prematuration medium is used to prepare the embryogenic culture for transfer to maturation medium and development of cotyledon stage embryos suitable for germination. In addition the embryogenic culture contains early stage embryos.

Attree teach a method of producing mature somatic embryos in all conifers including *Pinus taeda, Picea glauca* (white spruce) and *Pseudotsuga menziesii* (Douglas fir) (col. 19, lines 1-2). Attree teach that immature somatic embryos of white spruce were precultured in 1/20 strength hormone medium for one week then transferred to maturation medium containing 3% sucrose, 20µM ABA and adjusted to 290 mmol/kg with PEG (polyethylene glycol). The third week of culture the white spruce somatic embryos were cultured in 3% sucrose, 30µM ABA, 10% PEG and 3.32% lactose (Table 5 and col. 26, lines 35-38). At this stage, this may be considered the prematuration step because it is after the proliferation step and before the maturation step and involves the reduction of auxin and cytokinin and/or change in water stress

with the addition of ABA (see p. 4 of specification of instant application). The additional sugar has been metabolized because the embryos developed. The embryogenic culture at this stage should contain early stage embryos. The nutrient medium at the third week in Table 5 has less auxin or cytokinin and has increase ABA. The embryos eventually germinated to produce root and epicotyl elongation (col. 30, lines 7-9).

Attree does not teach that the nutrient medium further comprises of auxin and cytokinin, wherein the prematuration medium contains less auxin and less cytokinin than the maintenance medium.

Handley et al teach a method of regenerating *Pinus taeda* in liquid medium, wherein the initiation (induction) (col. 5, lines 62-64) and maintenance (col. 6, lines 7-9) media contain sugar selected from the group consisting of glucose, maltose (6% see Table 2), sucrose (3% see Table 2), melezitose, and combination thereof, which would include at least two types of sugars and the development (prematuration) (col. 6, lines 16-25) medium contains sugar selected from the group consisting of glucose, maltose, sucrose, and combination thereof, which would include at least two types of sugars (emphasis added). The maintenance medium also contains 0.1 to 100 mg/l of auxin and 0.05 to 10 mg/l of cytokinin (col. 6, lines 5-6 and Table II). The prematuration medium further comprises between 5 to 250 mg/l of ABA (col. 6, lines 17-18) and no auxin and cytokinin (Table II). The prematuration medium contains ABA and less auxin and less cytokinin than the maintenance medium. At weeks 6, 9 and 12, the embryos were suitable for germination (col. 17, lines 66-67). The somatic embryos were allowed to further develop with ABA and the development of cotyledon was noted (col. 19, lines 60 to col. 20, line 30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to reproduce coniferous somatic embryos wherein the nutrient medium contains lactose and additional sugar as taught by Attree and to modify the prematuration medium containing

ABA and no auxin and cytokinin when compared to the maintenance medium containing auxin and cytokinin as taught by Handley. It would have been obvious to one of ordinary skill in the art to use lactose in the culture medium as taught by Attree and then add additional sugar such as sucrose or glucose to the initiation and prematuration medium as taught by Handley et al. The additional sugars selected were readily metabolized because the embryos developed. One of ordinary skill in the art would have been motivated to do so given that ABA is a growth regulator and auxin and cytokinin is not needed in the prematuration stage. With regard to the amount of lactose in the nutrient medium of less than 2.0%, it would have been obvious to one of ordinary skill in the art to use less lactose because Attree disclosed that for embryo development it is preferred that less than 3% of sucrose and equivalent well-metabolizes carbon sources could be used (col. 11, lines 57-60). Thus, less than 2% equivalent well-metabolize carbon source such as lactose is acceptable. One of ordinary skill in the art would have been motivated to use less than 2% lactose in the nutrient medium because a minimum of 3% of total carbohydrate in the nutrient medium is necessary for the development of embryos (Attree col. 11, lines 57-60). Thus, the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' arguments filed on November 13, 2007 have been fully considered but they are not persuasive.

Applicants urge that the Attree reference refers to the maturation medium and not the induction, maintenance or prematuration medium as cited in the instant claims and that Handley et al do not teach induction, maintenance or prematuration medium containing lactose and additional sugars (response p. 12).

This is not found persuasive because Attree was combined with Handley et al which taught a method of regenerating coniferous plants wherein the induction and prematuration

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cultures contain a combination thereof glucose, maltose and sucrose. As stated above a combination thereof would contain at least two types of sugar. It would have been obvious to use different types of sugar in the induction, maintenance or prematuration medium because Attree had shown that lactose and additional sucrose helped in the maturation medium and it would have been obvious to try lactose and additional sucrose in the induction, maintenance or prematuration medium.

Applicants urge that adding lactose to the medium would not have been expected to benefit the somatic embryogenesis (p. 13 of reply).

This is not found persuasive because Attree had shown that lactose used in the culture medium had benefited the development of the embryos whether or not lactose was believed to be metabolized by coniferous somatic embryos.

Claims 50-54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Fan et al (U.S. Patent No. 6,689,609) in view of Handley et al (U.S. Patent No. 5,491,090).

The claims are drawn to a method of reproducing somatic embryo *Pinus taeda* or hybrid thereof comprising growing an explant in induction, maintenance or prematuration medium, comprising of between 1.0% and 6.0% lactose for the development of the explant to the cotyledon stage suitable for germination.

Fan et al teach a method of nutripriming somatic embryos of pines and spruces (Example 4) to produce full-grown plants. The seeds are imbibed in water (initial phase or phase one) then the somatic embryos from the seeds are transferred to nutripriming solution for phase two comprising a carbohydrate source such as lactose (col. 10, lines 43-58) at a range of 3-6% (w/v). Phase two is the growth of the zygotic embryos (col. 9, lines 15-17) similar to the maintenance step, wherein the embryos are grown.

Fan et al do not teach that the somatic embryo is *Pinus taeda* or hybrid thereof and that lactose is used in the initiation and prematuration media.

The teachings of Handley et al are discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of reproducing coniferous somatic embryos wherein the nutrient medium comprises of lactose in the maintenance medium as taught by Fan and to modify the method by using *Pinus taeda* as the explant as taught by Handley. It would have been obvious to one of ordinary skill in the art to try lactose as taught by Fan in the initiation and prematuration media because if lactose helped in maintenance medium then it would have been obvious to try lactose with the other media. One of ordinary skill in the art would have been motivated to do so given that *Pinus taeda* is an important timber crop. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of Fan and Handley because if it had worked on other species of pines then it would work for *Pinus taeda*. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' arguments filed on November 13, 2007 have been fully considered but they are not persuasive.

Applicants urge that Fan indicates that the starting material is dessicated mature plant somatic embryos (p. 14 of reply).

This is not found persuasive because the claims cite coniferous somatic embryos and do not state the age of the starting material.

Applicants urge that Fan does not teach or suggest using medium comprising lactose in the induction, maintenance or prematuration steps of somatic embryogenesis (p. 14 of reply).

This is not found persuasive because the maintenance medium is defined in claim 50 as growing and maintaining embryogenic culture. In Fan, as stated above the embryos are grown in medium containing lactose (col. 10, lines 55-60).

Applicants urge that Handley does not cure the deficiency of Fan (p. 14 of reply).

This is not found persuasive because Fan was combined with Handley to show that lactose can be used in the maintenance medium with good results with *Pinus taeda* or hybrid thereof.

Claims 55-60 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Coke (U.S. Patent No. 5,534,433) in view of Pullman et al (U.S. Patent No. 6,492,174).

The claims are drawn to a method of reproducing somatic embryo by somatic embryogenesis selected from the group consisting of maintenance medium and prematuration medium, wherein the nutrient medium comprises between 1.0% and 6.0% of galactose-containing sugar and an additional sugar wherein the coniferous somatic embryo is selected from *Pinus radiata* or hybrid thereof and *Pseudotsuga menziesii* and hybrid thereof, and developing the explant to obtain a cotyledon stage embryo suitable for germination.

Coke teaches a basal nutrient medium for embryo development (maintenance medium) of *Pinus taeda* (loblolly pine), wherein two sugars are added to the nutrient medium (sucrose (30g/l) and maltose (60 g/l)) (col. 6, lines 59-62). After nine weeks of embryo development Coke collected data on the number of cotyledon stage embryos (col. 7, lines 37-40 and Table VI).

Coke does not teach galactose-containing sugar, wherein the coniferous somatic embryo is selected from the group consisting of *Pinus radiata* or hybrids thereof and *Pseudotsuga menziesii* or hybrids thereof.

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Pullman et al teach a method of initiating embryogenic cultures of *Pseudotsuga menziesii* (Douglas fir) (Example 2), and *Pinus radiata* (col. 7, line 44) (Example 3), wherein the explant is induce in liquid media containing between 5 and 70 g/l of maltose (for example 1.5% see Table 47), glucose, fructose, sucrose (for example 1% - 1.5% see Table 3 and 5), galactose, or combination thereof (col. 9, lines 54-58), which would include at least two sugars one being galactose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to reproduce coniferous somatic embryos, wherein the nutrient medium contains two sugars as taught by Coke and to modify the sugars by using galactose as the primary sugar as taught by Pullman and then using sucrose or maltose as the secondary sugar as taught by Coke. Furthermore, Pullman noted that galactose or combination thereof maltose, glucose, fructose, and sucrose are effective carbohydrate energy source (col. 9, lines 54-57). One of ordinary skill in the art would have been motivated to do so given that sugar is necessary for further development of conifer embryos. Furthermore, one of ordinary skill in the art would have a reasonable expectation of success in the combination of using galactose as the primary sugar and using sucrose or maltose as the secondary sugar, because Pullman states that a combination of sugar could be utilized (col. 9, lines 54-56). Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicants' arguments filed on November 13, 2007 have been fully considered but they are not persuasive.

Applicants urge that the maturation medium contains two sugars, sucrose and maltose, neither which is galactose-containing sugar and not the prematuration medium (p. 15 or reply).

This is not found persuasive because claim 55 cites that the maintenance medium is used to grow and maintain the embyrogenic culture. Coke cites the nutrient medium for embryo

development (col. 6, lines 59-63), which would be similar to the maintenance medium of the instant invention because the embryo is growing or developing in the medium containing two sugars.

Applicants urge that Coke does not teach or suggest using more than one sugar in the maintenance or prematuration steps and does not teach or suggest using galactose-containing sugar in any step (p. 15 of reply).

This is not found persuasive because one cannot show nonobviousness by attacking the references individually where the rejection is based on a combination of references. Coke taught a method of culturing loblolly pine, wherein the basal nutrient medium for embryo development (maintenance medium) contains two sugars and was combined with Pullman who taught using galactose-containing sugar for embryo culture of *Pinus radiata* or hybrids thereof and *Pseudotsuga menziesii* or hybrids thereof.

### Conclusion

No claims are allowed.

## Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to June Hwu whose telephone number is (571) 272-0977. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached on (571) 272-0975. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

ANNE KUBELIK, PH.D.